MICHIGAN ENVIRONMENTAL SCIENCE BOARD

COUNCIL OF GREAT LAKES GOVERNORS SPECIAL FISH ADVISORY PANEL
MEETING SUMMARY
FRIDAY, JANUARY 20, 1995
SHERATON LANSING HOTEL
LANSING, MICHIGAN

PANEL MEMBERS PRESENT
Dr. Lawrence Fischer, Chair
Dr. Michael Bolger
Dr. Gary Carlson
Dr. Joseph Jacobson
Dr. Barbara Knuth
Dr. Martha Radike
Dr. Mark Roberts
Dr. Peter Thomas
Dr. Kendall Wallace
Mr. Keith Harrison, MESB Executive Director

PANEL MEMBERS ABSENT
None

DMB/EAD SUPPORT STAFF PRESENT
Mr. Jesse Harrold, Environmental Officer
Ms. Patricia Hiner, Secretary
Mr. Alex Morese, Graduate Student Intern

I CALL TO ORDER

Mr. Keith Harrison, MESB Executive Director, called the meeting of the Special Fish Advisory Panel to order at 9:00 a.m.

II EXECUTIVE DIRECTOR'S REPORT

Mr. Harrison indicated that he had no report.

III PRESENTATION

Mr. Charles Pistis, District Extension Agent for the Michigan Sea Grant Program, provided an overview of the decline which has taken place in the Great Lakes fishery and its impact on exposure from fish consumption. A summary of his presentation may be found in Attachment 1.

Dr. Knuth asked how the sizes of fish used in the advisories relate to the sizes most commonly targeted through the charter boat industry. Mr. Pistis indicated that for chinook salmon, for instance, the average size is about 10 pounds. In general, the age and length of fish currently caught have decreased.

Dr. Carlson expressed concern regarding how some of the numbers were obtained in the Smith (1995) unpublished manuscript.

Dr. Jacobson asked what was the source for the decline in the Great Lakes fisheries resource. Mr. Pistis stated that there were several theories, including introduction of exotics and therefore increased competition for resources, reduced lake productivity, culturing practices in the fish hatcheries. Economic recession has also been attributed as having impacted the amount of fish being taken from the Great Lakes.

IV PANEL DISCUSSION ON DIRECTIVES

Dr. Fischer discussed the tasks before the Panel in drafting the report to the Council of Great Lakes Governors and asked for comments from the Panel members.

Dr. Knuth stated that she had initially interpreted Council of Great Lakes Governors' Directive 3 as requiring the Panel to prepare a new fish consumption advisory if the proposed Protocal was found to be unacceptable. If that is not the case, however, she believes it necessary to suggest specific changes or alternatives to methodological elements contained in the proposed *Uniform Great Lakes Sports Fish Consumption Advisory* (Protocol) based on the Panel's criticisms. Dr. Fischer agreed, indicating that it never has been his interpretation that the Panel was supposed to prepare a new fish consumption advisory in response to Directive 3. He envisioned the Panel's response to Directive #3 more along the lines of listing the necessary changes to the Protocol based on the conclusions reached by the Panel to, in particular, Directive #1. The actual mechanics of revising the Protocol and creating a new document would necessarily need to be that of the Great Lakes Fish Advisory Task Force (Task Force).

Dr. Fischer asked the Panel members to provide an overview of their initial or preliminary evaluation of the data used and the scientific validity of the conclusions reached in the Protocol.

Dr. Thomas indicated that from his perspective the overall process and the studies used in proposed Protocol appeared reasonable. The consumption values used reflect the state of the science, the effects on the immune system seem reasonable, and the process used to extrapolate from a Lowest-Observed-Adverse-Effect Level (LOAEL) to a No-Observed-Adverse-Effect-Level (NOAEL) appeared justified.
Dr. Jacobson asked Dr. Thomas if accumulated subtle changes in the toxicological end points were enough to eventually impact the immune system's ability to fight disease. Dr. Thomas indicated that minor changes were not very significant. In the case of dioxin, experimental animal studies show that the host defense seems to be the most

significant and sensitive end point following exposure to TCDD. At this point, this effect cannot be demonstrated in humans and it's difficult to extrapolate up. No single test result can be predictive; it has to be looked at in the context of other toxicological end points.

Given the existing animal data on the impact on the immune system, Dr. Jacobson asked whether Dr. Thomas would suggest that humans could be expected to get sick at current levels of exposure. Dr. Thomas indicated that the question was difficult to answer, but they probably would not. In the animal studies there is some indication that there are dose-related changes and that some of those are occurring at exposure levels found in the environment. The difference is that laboratory conditions are very controlled, and subtle effects can become apparent. Science cannot yet predict whether there will be adverse effects in humans. Such effects have not been seen in epidemiological studies.

Dr. Bolger questioned the usefulness of the animal studies in the process of setting the Protocol. Without human studies, uncertainty factors have to be applied, and that is in the realm of value judgement, not science. A safety assessment is not really a quantitative risk assessment. He indicated that the Panel should keep trying to do a quantitative risk analysis.

Dr. Radike discussed the Canadian Rhesus monkey data, noting that it appeared flawed. Dr. Bolger pointed out that flaws can be found in any study, and that while it is not clear whether the monkeys' compromised immune function was the result of the exposure or of the aging process, or the result of sheep red blood cells, the results were in line with results derived from other, different, approaches. The problem is the methodological approach being used, where safety, rather than the specific dose-response relationship, is driving the analysis. The human studies showing the risk at different levels of exposure have not been done. Without these types of data, it becomes very difficult to generate a realistic Protocol.

Dr. Carlson expressed concern about the changing basis (Jacobson data versus Rhesus monkey data) for the development of the proposed Health Protection Value (HPV). It may be that the number fits both data sets. The Panel has previously heard about some of the concerns with the Jacobson data. Within the Rhesus monkey study, the significant factor was sheep red blood cells but even here, several of the reviewers in the first round comments on the Protocol criticized the sheep red blood cells as an inappropriate testing mechanism. Dr. Thomas indicated that the test is commonly used and very consistent in terms of exposure levels versus effect. It is a measure of immunity and ability to generate an antibody response. However, it cannot be used alone to indicate that the immune system is at risk. Other factors must be measured, and he thinks the Rhesus monkey studies did that. There may be too much emphasis placed on the sheep red blood cell test. The primary advantage of the study is that it used primates rather than rodents. The criticism he has for the study is that he would like to have seen a demonstration of more than one host defense type measure affected

before concluding an increased risk. The Rhesus monkey study had trouble showing this.

In light of the fact that a positive response does not in and of itself indicate increased risk, Dr. Wallace asked whether or not a lack of response indicates that no risk is present. Dr. Thomas answered that the data need to be interpreted on a continuum, and that one measure cannot be definitive. Dr. Bolger agreed that a decision should not be based on one end point. He also noted that there was inadequate knowledge of the effect of the aging process itself on the immune system, and the Rhesus monkeys were aged.

Dr. Radike said that one criticism of the Rhesus monkey study was that the authors relied on the use of an inappropriate antigen, sheep red blood cells, as an indicator of the health of the animal's immune system. Only the pneumococcal antigen is relevant to the primate immune system as it tests a number of immune functions including antigen presentation, T-cell and B-cell functions, and the expression of antibodies. Dr. Thomas responded that he agreed in part with her comments.

Dr. Fischer asked Dr. Thomas if he was suggesting that it was not possible to detect immunological impairment in the human population with current tests because of the background noise involved. Dr. Thomas responded that the mouse model is very clear and has been used for 30 years. The available epidemiological evidence however does not convince him that reproducible significant dose-related changes in humans exposed to PCBs from the Great Lakes can be detected. The laboratory tests are valid and results can be extrapolated to humans with uncertainty factors, but with current tests and uncertainties he does not think the effects can be seen in humans.

Dr. Fischer asked Dr. Thomas if effects could be seen in high exposure situations, such as occupational exposures. Dr. Thomas answered that very high exposures to pesticides do produce evidence of immunological effects in humans manifested as hypersensitivity. Hypersensitivity reactions are seen more in terms of immune stimulation rather than suppression. Dr. Bolger pointed out that among PCB workers, chloracne is found with no sign of immune compromise. Dr. Roberts cautioned about generalizing to a population based on worker exposure data.

Dr. Fischer asked Dr. Thomas if the HPV was sufficiently low to protect from an immunological end point. Dr. Thomas indicated that his immediate reaction, without doing any calculations, was that it was reasonably protective.

Dr. Jacobson indicated that the HPV is defensible for women of child-bearing age and children, but may be overly restrictive for the rest of the population. There appears to be no data supporting neuro-behavioral effects on women of child-bearing age or males. Dr. Thomas pointed out that not much is known about prenatal or perinatal exposure. Dr. Fischer agreed, stating that he was not aware of any animal studies which measured immune function after prenatal exposure.

Dr. Fischer moved the discussion to the topic of health outcomes, in particular neuro-behavioral. He asked Dr. Jacobson to discuss the animal data showing neuro-behavioral effects, and to elaborate on his opinion regarding the proposed HPV and it's applicability to children, women of child-bearing age, and the population at large. Dr. Fischer also questioned whether the data had been reproduced in other studies. Dr. Jacobson commented that a major finding in his research was the vulnerability of the fetus compared to that of the infant. Therefore, the HPV was very reasonable for the protection of the fetus and women of child-bearing age. This protection might even be extended to children, but with little scientific basis. As for the general population, there appeared to be little justification for such a high level of protection.

Dr. Jacobson indicated that in a comparison of length of breast feeding time of infants whose mothers had a lot of PCB in the milk, the infants who were breast fed for a long period of time did better than the ones who were breast fed for a short period of time; heavier doses of postnatal PCBs resulted in better performance. The reason was that the mothers who breast fed for a long time were also giving the children better stimulation. The importance of this finding is that all the PCBs that the mothers were exposing their children to did not harm them in any way that could be discerned while much smaller quantities of prenatal exposure to PCBs resulted in very significant effects. The researchers of the Jacobson study felt that the picture was clear that the fetus is much more vulnerable. The decision of discriminating with the fish advisories between women of child-bearing age came out before the Jacobson study was completed. The Jacobson study just confirmed that that was the way to go. Dr. Jacobson expressed concern about the way his study's results have been expanded on by some to somehow now apply to everyone because that interpretation goes so much against what his data are actually stating.

Concerning other research findings, Dr. Jacobson commented on the Rogan study indicating that its findings could be interpreted as indirect confirmation with his study. The Rogan study saw effects on different and fewer end points than he did in his study, however.

Dr. Carlson stated that his expertise was in the area of risk assessment not risk management. From a risk assessment perspective, he felt confident that the proposed HPV would adequately protect human health, but felt it could be higher and still be protective. Dr. Carlson reiterated Dr. Jacobson's statement that protecting women of child-bearing age and protecting the general public were two different issues.

Dr. Wallace suggested that if the Panel was to follow the Governor's charge, it should concentrate less on the HPV and more on the process that was used to select the value. The process used by the Task Force appears to be more political than scientific in nature. There was no well-designed scientific approach.

Dr. Knuth stated that the process by which the HPV was determined, although probably not reproducible, was reasonable considering the number of jurisdictions and agencies that were involved. She continued with suggestions to improve the risk communication

aspect of the Protocol. First, the Protocol's relation to commercial fish consumption should be explained. Second, an increase in the amount of information concerning the health benefits associated with eating fish, was needed. An explicit description of what the health benefits are and to whom the benefits are most important (elderly vs. women of child-bearing age). Along this line, what types of illnesses the advisory is protecting against (cancer, reproduction, etc.), and who the advisory is targeted towards should be illustrated better. Lastly, an important element presently excluded, was pretesting to see how certain groups react to each presentation of information. If the purpose of an advisory is to allow people to make their own informed decision about fish consumption, the uncertainties about the data or science should also be portrayed.

Dr. Wallace inquired if the intent of the advisory was to change behavior or to inform the public. Dr. Fischer stated that Dr. Vernon Miller implied that readers of the advisory became informed but their behavior generally remained as it was before. Dr. Knuth indicated that one problem in Dr. Miller's survey of angler response to the advisory was that he did not have a baseline to work from. Dr. Knuth stated that her work indicates that about 30% of Great Lakes anglers that catch and eat large salmonoids believe that they are within the advisory and in fact they are not. This determination was made from a 12-month recall survey. She believes a goal of 90% public comprehension of an advisory would be realistic. Ideally, the objective is to allow people to make their own informed decisions. A quantitative risk assessment would be quite explicit, but the data are not expressed in a graduated manner so the generation of an accurate quantitative expression would be impossible. A few anglers would like a scientifically explicit advisory which would express doses for 1 in 10,000, 1 in 100,000 and 1 in 1,000,000 health or cancer risk. Furthermore, if one is lead to believe that six meals a year are OK, then what happens with meal number seven.

Dr. Wallace questioned whether the Protocol should be more of a quantitative risk assessment rather than a safety assessment. Dr. Fischer stated that the Protocol was based on a dose response relationship, but the risk was not explicit and the terms such as, birth defects, learning defects and cancer invoke a reaction in people regardless of the risk reality.

Dr. Bolger suggested that a table should be incorporated into the Protocol showing a relationship percentage of reasonable safety, with a lesser percentage of safety associated with a greater consumption of fish.

Dr. Roberts indicated that the amount of raw data and samples taken to determine the HPV is inadequate. The Panel should acquire scientifically justifiable numbers first and then look at who is being effected. The HPV errs on the safe side of public health. The great value in the dietary quality of fish protein must be considered also because the replacement for it may well be worse health-wise, than the questionable effects of the contaminants in Great Lakes fish. A diet containing fish contributes to high quality breast milk which is extremely important to the infant in the first few months of breast feeding.

Dr. Bolger brought up the issue of the Governor's second charge to the Panel regarding the comparative risks of other replacement foods and that the nutritional value of fish should be considered in these advisories. He reiterated the need for health benefit data on fish consumption adding that 20 years ago a tribe of Native-Canadians was forced off a basic local fish diet and on to other foods resulting in an epidemic level of the disease diabetes.

Dr. Fischer stated that the Protocol should be open to change, capable to absorbing new data and have a standardized process to evaluate old and new data, from year to year. This would provide more consistent and justifiable numbers among states. This process should be applicable to any chemical, accommodate new driver compounds and have provisions for hot spots.

Dr. Wallace added that an established process would eliminate contention. Dr. Roberts indicated that he would be much more comfortable approving a process than a number.

Dr. Bolger explained the federal Food and Drug Administration's (FDA) position on PCBs in fish, as compared to that of the U.S. Environmental Protection Agency's (USEPA). He stressed that the two agencies' approach the issue differently. While the USEPA safety number is based solely on hazard, the FDA has to consider other relevant information such as economics. It needs to balance the health assessment against the economic consequences of what is proposed. Presently, the health benefits of fish consumption are not included in the FDA equation, but future tolerance levels will integrate this information.

V PUBLIC COMMENTS AND QUESTIONS

Dr. Hal Humphrey, Michigan Department of Public Health (MDPH), raised the point of comparative risk such as wearing seat belts to eating contaminated fish. Dr. Knuth replied it is generally thought that such comparisons are only marginally effective in terms of the public and there were no empirical data to support a comparative risk illustration.

Mr. Hesse, MDPH, stated his objection to the establishment of an evaluation process; indicating that it would result in a cook book approach.

Dr. Larry Holcomb, Holcomb Environmental, commented that the conclusions in the Protocol are all tentative and the tentative conclusions are based on tentative findings. Second, it has been admitted that the proposed HPV was derived by using multipliers, which means that no effect has been displayed by the use of this number on experimental animals or humans. Third, an established evaluation process would be germane.

Mr. Wayne Schmidt, National Wildlife Federation, appealed to the Panel to agree with the conservative finding of the Task Force because of all the unknowns involved in reaching a conclusion.

Dr. Milton Clark, USEPA, stated that the USEPA was in favor of the proposed Protocol and the HPV because the presently used fish advisories were not protective enough. USEPA concludes that the current marketplace value of a cancer risk of 1 in 10,000 is reasonable and the Protocol provides such protection. The Protocol standard is very close to the same level for maximum contamination of drinking water, an intake of 3.5 _g/day/70 kg body weight.

Dr. Carlson commented that he was not comfortable imposing the idea that the reasonable consumption of Great Lakes fish would be a health hazard. He reiterated Dr. Jacobson's suggestion that the Protocol should call for two numbers - one for women of child-bearing age and another for the less impacted portion of the society.

Dr. Bolger stated that the changing of a fish from once a week consumption to once a month could create a confidence problem with the Protocol and will probably not reduce the fish consumption per family.

Mr. Harrold (MESB) suggested that it would be easier to move a fish species within non-numbered classifications such as: "very limited consumption", " moderate consumption" and "unlimited consumption rather than in a classification of meals 1/week, 1/month or 1/year. If an angler requests a more scientific expression it can be made available upon request.

Dennis Leonard, Detroit Edison, stated that he supported the notion of developing a better process even if PCBs were the only pollutant for the majority of Great Lakes. However, there are other contaminants which are and/or will need to be regulated. There is a need for the development of a consistent process which is based in science, understood and applicable to use with other contaminants.

VI NEXT MEETING DATE

Mr. Harrison indicated that the next meeting of the Panel will be held in Chicago. The date will be determined based on a telephone poll of the Panel members.

VII ADJOURNMENT

The meeting was adjourned at 4:00 p.m.

Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board

Attachment 1. Presentation by Mr. Charles Pistis, Sea Grant Extension Agent from the Michigan Sea Grant Programs, to the Council of Great Lakes Governors Special Fish Advisory Panel.

With the decline of Great Lakes fishery, the charter boat industry has declined - from 1,000 boats in 1986 to 543 today. Preliminary data from a 1994 Great Lakes Charter Boat Survey by the Great Lakes Sea Grant Network indicates that 70% of respondents ranked lack of fish as the worst problem for the charter fishing industry, 42% ranked fisheries management first, and 38% ranked fish consumption advisories first.

Mr. Pistis discussed a data set collected by the MDNR Fisheries Division for the period 1985 to 1992, which indicated that the Lake Michigan fishery has declined substantially since 1986. He indicated that, as a consequence, calculations of exposures, number of meals consumed, types of species consumed need to also change and be reflective of current conditions. It is important that the Panel have the most recent data when looking at estimates of exposure. He calculated consumption from creel census data, which was obtained by counting actual fish caught, rather than using data obtained by asking people how much fish they thought they had eaten during a given period of time. Assuming that the edible portion is 40% of the poundage caught, he calculated that fish consumption is about 2.3 g/day; much lower than estimates currently being used as a basis for fish advisories. For instance, West's 1993 research, based on a survey of 7,000 anglers, calculated a consumption rate of 14.5 g/day.

Mr. Pistis also discussed another estimate by Smith (1995 unpublished manuscript) which used Lake Trout to demonstrate a discrepancy between the amount of fish the lakes can produce and the amounts being used to calculate exposures, saying that the lakes cannot produce enough to produce those exposures.

Copies of Mr. Pistis' overheads are appended to this attachment.